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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,514	02/21/2003	Robert T. Belly	60/132,443	1153

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/019,514	<b>Applicant(s)</b> BELLY ET AL.	
	<b>Examiner</b> Young J. Kim	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/7/02 &amp; 5/5/04</u> <u>3/2/04</u> | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-6 in the reply filed on May 16, 2005 is acknowledged. The traversal is on the ground(s) that there exists a special technical feature between claims 1-6 and 7-9, involving one or more of the same of corresponding "special technical features," wherein the special technical features is argued as being without the use of a lysing agent.

Applicants' arguments do not include claims 10-22, which were grouped together with claims 7-9 as Group II nor an election of a set of SEQ ID Numbers (two SEQ ID Numbers), as required in the Restriction requirement mailed on April 28, 2005, further confounding as to whether Groups I and II should be joined together. This interpretation is assumed in rebuttal of Applicants' arguments.

With respect to Applicants' arguments drawn to the rejoinder of claims 1-6 and 7-22 (entire Group II), Applicants arguments are not found persuasive for the following reasons.

MPEP 1850, in discussing unity of invention states the below statement regarding "categories of claims" (not categories of invention):

(A) Combination of different categories of claims.

This "combination" is further described by the same section of the MPEP as being:

(A) a product, a process specially adapted for producing the product, and a process specially adapted for the use of the product;

(B) a process, an apparatus or means specially designed for carrying out said process;  
and

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(C) a product, a process specially adapted for the manufacture of said product, and an apparatus or means specially adapted for carrying out the process.

MPEP explicitly states that, “[m]ore extensive combinations than those set forth above should be looked at carefully to ensure that the requirements of both PCT Rule 13 (unity of invention) and PCT Article 6 (conciseness of claims) are satisfied. *In particular*, while *a single set* of independent claims according to *one of* (A), (B), or (C) above is *always permissible*, it *does not require the International Authority to accept a plurality of such sets* which could arise by combining the provisions of PCT Rule 13.3.

Clearly, claims 1-6 is drawn to a single process of extracting a nucleic acid, while claims 7-21 is drawn to *an additional* process of not only extracting nucleic acids, but also amplifying employing a specific set of primers whose patentability is based on the make up of the actual primers (*i.e.*, SEQ ID Numbers). Additional products, its uses, apparatus, or processes of making said product, are not required to be accepted.

If Applicants’ assertion were to be valid, there would exist unity of invention between a method of extracting DNA via use of a specific condition, and *any* nucleic acid detection methods involving the same nucleic acid extraction steps. If this were true, the Office must examine diagnosis of any diseases and condition, or amplification assay for *any and all* target nucleic acids as most of the detection/amplification assays involve extraction nucleic acids.

The restriction practice is consistent with that which is described in MPEP 1850, governing the restriction practice with regard to International Application and National Stage application filed under 35 U.S.C. 371.

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For the above reasons, the requirement is still deemed proper and is therefore made FINAL.

Claims 7-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 16, 2005.

### ***Information Disclosure Statement***

The IDS received on February 7, 2002 and May 5, 2004 are acknowledged.

With regard to the two U.S. Applications cited in the IDS received on March 2, 2004 (Higuchi and Ekeze et al.), 37 CFR 1.98(a)(iii) indicates that for each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion be provided. Additionally, 37 CFR 1.98(b) states that each U.S. application listed in an information disclosure statement must be identified by the inventor, application, and filing date.

The IDS received on March 2, 2004 does not comply with the requirements of the above-cited section of the 37 CFR, and therefore, have not been considered.

### ***Drawings***

The drawings filed on October 26, 2001 are acceptable.

### *Claim Interpretation*

The term, "about" is defined as a variance of 110% of the noted values (page 13, lines 9-10). With regard to the term, "about," being associated with pH, the term is defined as +/- 0.5 pH unit (page 13, lines 10-11).

### *Specification*

The specification is objected to for the following reasons.

On page 38 of the instant specification, Applicants appear to disclose a comparison of the DNA extracted from white blood cells (WBC) between the method involving the use of a lysing reagent (control) and the method of the instant invention.

While the method of extracting DNA via use of lysing reagent is discussed in detail, the method involving the instant invention is not disclosed. Specifically, on page 38, the following is disclosed.

#### METHOD OF INVENTION - NO USE OF LYSING REAGENT

Samples not contacted with lysis reagent were treated as follows: the pellet from each of four separate tubes was resuspended in 100  $\mu$ L of PBS.

Samples prepared using both above-methods were processed identically: the tubes were centrifuged at 14,000 rpm for 2 min, the supernatant fluid from each tube was carefully decanted into new tubes and stored at room temperature prior to analysis. DNA content for each tube was analyzed using the TaqMan  $\beta$ -actin assay and an ABI Prism 7700 Sequence Detector as described above, with calibration based on DNA standards purchased from Perkin Elmer. The results are summarized in Table IV.

The specification states that samples not contacted with lysis reagent were treated as follows: the pellet from each of the four separate tubes was resuspended in 100  $\mu$ L of PBS. It appears that the description of the instant invention is missing.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting the phrase, “without the use of a cell lysing reagent,” because it is unclear how nucleic acids, which are enclosed in a cell membrane (whether prokaryotic or eukaryotic) could be extracted without first disrupting the cell membrane, hence all reagents must first lyse the cell.

Clarification is requested.

Claim 1 is indefinite for reciting the phrase, “ethylenically unsaturated,” because it is unclear what is meant by this phrase.

Claim 1 is indefinite for reciting the phrase, “method for providing a nucleic acid from a sample without use of a cell lysing reagent comprising the steps of...at a pH of less than 7, contacting a sample..with a water-soluble, weakly basic polymer...” because it is unclear what element actually comprises pH of less than 7. According to the specification, a sample (suspected of containing a nucleic acid) is admixed with a buffer at below pH of about 7.0 (page 10, 2<sup>nd</sup> paragraph). This interpretation is assumed therefore for the purpose of prosecution.

Claims 2-6 are indefinite by way of their dependency on claim 1.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Backus et al.

(U.S. Patent No. 5,582,988, issued December 10, 1996).

Preliminarily, the instant rejection is based on the following claim interpretation.

The method is recited as being drawn to providing a nucleic acid from a sample without use of a cell lysing reagent, comprising the recited steps (A), (B), and (C) of claim 1. The claim does not limit what is embraced by the term, "sample." So long as the nucleic acid is provided from a sample without the use of a lysing reagent, comprising the recited steps, prior art would properly anticipate the invention as claimed.

The method disclosed by Backus et al. provides nucleic acid from a cell lysate, which is also embraced by the general term, "sample" employed by instant claims, wherein the method employs non-lysing reagents (as will be discussed below).

Particularly, Backus et al. disclose a method of providing a nucleic acid from a sample, comprising the steps of:

A) at a pH of less than 7, contacting the sample suspected of containing a target nucleic acid with a water-soluble, weakly basic polymer in an amount sufficient to form a water-insoluble precipitate of the weakly basic polymer with all nucleic acids present in the sample, including the target nucleic acid (column 2, lines 20-24);

B) separating the water-insoluble precipitate from the sample, (column 2, lines 25-26)  
and

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C) contacting the precipitate with a base to raise the solution pH to greater than 7, and thereby releasing the nucleic acids, including the target nucleic acid, from the weakly basic polymer (column 2, lines 27-30),

The weakly basic polymer comprising recurring units derived by addition polymerization of one or more ethylenically unsaturated polymerizable monomers having an amine group which can be protonated at acidic pH (column 2, lines 30-35).

With regard to the certain weight percentages of the monomers added to produce the “weakly basic” polymer, such is a product produced by the process and as the weakly basic polymer of the Backus et al. achieves the identical result, the products are determined to be the same.

With regard to claim 2, Backus et al. disclose that the pH of the solution containing the released nucleic acid could be adjusted from about 6 to about 9 (column 5, lines 45).

With regard to claim 3, the base is disclosed as being, for example, sodium hydroxide (column 5, lines 13-22).

With regard to claim 4, Backus et al. disclose that the weakly basic polymer used in an amount from 0.01 to about 0.5% weight (column 4, lines 48-51).

With regard to claim 5, a weak base is accompanied by heating of about 50° to about 125° (column 5, lines 23-27).

With regard to claim 6, strong base is used without heating in releasing the target nucleic acid from the weakly basic polymer (column 5, lines 40-45).

Therefore, the invention as claimed is clearly anticipated by Backus et al.

### ***Conclusion***

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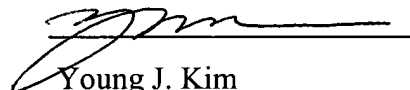
No claims are allowed.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim  
Patent Examiner  
Art Unit 1637  
6/11/2005

**YOUNG J. KIM  
PATENT EXAMINER**

yjk